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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,059	05/22/2000	William J. Curatolo	PC8626BJTJ	2926

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03/08/2005

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,059

Applicant(s)

CURATOLO ET AL.

Examiner

Frank I. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-148 is/are pending in the application.
- 4a) Of the above claim(s) 77-79, 87-92, 130-132 and 140-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-76, 80-86, 93-129, 133-139 and 146-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 72-148 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/2003</u> . | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 72-76,80-86,93-129,133-139, and 146-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handsfield et al. in view of Urquhart (US Pat. 4,851,231), Edgren (US Pat. 4,522,625) for the reasons of record set forth in the prior Office Actions in further view of Etienne et al. (US Pat. 4,755,385) and Periti et al. (Abstract) and the further reasons below.

Handsfield, Urquhart and Edgren are cited for the same reasons as the prior Office Action and the same are incorporated herein.

Etienne et al. disclose many macrolide antibiotics, such as erythromycin and AS-E 136 are sensitive to acidic media and are usually destroyed by the action of gastric juices (Column 1, lines 34-38). It is disclosed that it is well known to compress active substances with suitable excipients to form a tablet and coat a tablet with gastric juice-resistant lacquers such as cellulose acetate phthalate or hydroxyl-propylmethylcellulose phthalate which after leaving the stomach the lacquer dissolves in the intestinal juices and the active substance is dissolved and resorbed (Column 2, lines 25-53). It is disclosed that resistant to gastric juices means that the preparation should release virtually no active substance for a period between 30 minutes and 2 hours and having a pH solubility of between 5.5 and 6.8 or which releases the active substance at a pH of between 5.5 and 6.8, preferably, between 6.0 and 6.4 (Column 4, lines 5-10,60-68, Column 5,

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lines 1-6). Tests are performed using USPXX apparatus at 100 rpm at pHs of 1.2, 4.5, 6.0, 6.2, 6.4 and 6.5 (Examples 1-8).

Periti et al. discloses that azithromycin is acid unstable (although exhibiting increased acid stability over older macrolide antibiotics) (Abstract).

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Curaltolo is no longer part of the rejection herein. Although erythromycin and azithromycin do have their differences, both erythromycin and azithromycin exhibit adverse gastric effects and are acid unstable (although azithromycin does have increased acid stability over erythromycin). As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to control the release of azithromycin to be released at least 30 minutes after ingestion so as to avoid adverse gastric effects and any acid instability by using an enteric coating which dissolves preferably at a pH of between 6.0 and 6.4. As such, one of ordinary skill in the art would expect that for enteric coatings which dissolve at pHs of greater than 6.0 that substantially no active agent will be released until the pH of the surrounding media, whether in vitro or in vivo, is at the appropriate pH. As such, such a dosage form will meet the criteria set forth in the claims.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-76, 80-86, 93-129, 133-139, 146-148 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-76 of U.S. Patent No. 6,068,859 in view of Handsfield, Etienne et al. (US Pat. 4,755,385) and Periti et al. (Abstract).

Claims 1-76 disclose a controlled release dosage form in which not more than certain amounts of azithromycin are released within a time period after ingestion. "Controlled release" is defined to not include dosage forms which release more than 70% of their contained azithromycin within one half hour or less (Column 2, lines 9-12).

Hansfield, Etienne et al. (US Pat. 4,755,385) and Periti et al. (Abstract) are cited herein for the same reasons as above and are incorporated herein to avoid repetition.

The difference between the claims of the US Patent and the claimed invention is that the claims of the US Patent do not recite in vitro characteristics. However, the prior art amply suggests the same as the prior art discloses using USP criteria for determining release of active agents in various pH and the desirability of formulations which release at pHs greater than 6. As such, one of ordinary skill in the art would expect that formulation prepared under said criteria

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would exhibit in vitro characteristics the same or similar to that set forth in the claimed invention.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of US Pat. 6,068,859 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

March 1, 2005



S. MARK CLARDY
PATENT EXAMINER
GROUP 1800 1616